

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference X-16250	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/US2004/038221	International filing date (day/month/year) 01/12/2004	(Earliest) Priority Date (day/month/year) 12/12/2003
Applicant ELI LILLY AND COMPANY		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 9 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box II).

3. ☒ Unity of invention is lacking (see Box III).

4. With regard to the title,

- ☐ the text is approved as submitted by the applicant.
- ☒ the text has been established by this Authority to read as follows:

SELECTIVE NOREPINEPHRINE REUPTAKE INHIBITORS FOR THE TREATMENT OF HOT FLASHES, IMPULSE CONTROL DISORDERS AND PERSONALITY CHANGE DUE TO A GENERAL MEDICAL CONDITION

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. _____
- ☐ as suggested by the applicant.
- ☐ as selected by this Authority, because the applicant failed to suggest a figure.
- ☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☒ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/038221

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K31/138 A61K31/4468 A61K31/5375 A61K31/4704 A61K31/538 A61K31/5415 A61K31/40 A61K31/4025 A61K31/445 A61K31/439 A61K31/5377 A61P15/12 A61P25/00 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61K A61P Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, CHEM ABS Data, BIOSIS, EMBASE, SCISEARCH, WPI Data, PAJ		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
E	✓ WO 2005/047272 A (ELI LILLY AND COMPANY; CAMPBELL, GORDON, IAIN; CASES-THOMAS, MANUEL, J) 26 May 2005 (2005-05-26) abstract page 19, line 1 - page 20, line 7 -----	1,2
E	✓ WO 2005/023802 A (ELI LILLY AND COMPANY; CLARK, BARRY, PETER; GALLAGHER, PETER, THADDEUS) 17 March 2005 (2005-03-17) abstract page 16, line 28 - page 17, line 31; claims ----- -/--	1,2
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex		
* Special categories of cited documents: *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art *G* document member of the same patent family		
Date of the actual completion of the international search 22 July 2005		Date of mailing of the international search report 01/08/2005
Name and mailing address of the ISA European Patent Office, P B 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel (+31-70) 340-2040, Tx 31 651 epo nl, Fax (+31-70) 340-3016		Authorized officer Hoff, P

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/038221

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
P,X	✓ WO 2004/035058 A (WYETH; DEECHER, DARLENE, COLEMAN; MERCHENTHALER, ISTVAN, JOSEPH; LEVEN) 29 April 2004 (2004-04-29) abstract page 4, paragraph 11 - paragraph 12 page 10, paragraph 36 claims 1,6,23	1-3
P,X	✓ WO 2004/035036 A (WYETH; DEECHER, DARLENE, COLEMAN; MERCHENTHALER, ISTVAN, JOSEPH) 29 April 2004 (2004-04-29) abstract page 5, paragraph 19 - page 6, paragraph 23; claims 1,4,13	1-3
A	✓ WO 02/078691 A (ELI LILLY AND COMPANY; WALLACE, OWEN, BRENDAN; GARNETT, TIMOTHY, JOHN) 10 October 2002 (2002-10-10) the whole document	1-3
A	✓ LOPRINZI C L ET AL: "Venlafaxine in management of hot flashes in survivors of breast cancer: a randomised controlled trial" LANCET, vol. 356, no. 9247, 16 December 2000 (2000-12-16), pages 2059-2063, XP004264310 ISSN: 0140-6736 the whole document	1-3
A	✓ QUELLA S K ET AL: "PILOT EVALUATION OF VENLAFAXINE FOR THE TREATMENT OF HOT FLASHES IN MEN UNDERGOING ANDROGEN ABLATION THERAPY FOR PROSTATE CANCER" JOURNAL OF UROLOGY, BALTIMORE, MD, US, vol. 162, no. 1, July 1999 (1999-07), pages 98-102, XP009026289 ISSN: 0022-5347 the whole document	1-3
A	✓ WO 02/40006 A (ELI LILLY AND COMPANY; THOMASSON, HOLLY, READ; MICHELSON, DAVID; READ,) 23 May 2002 (2002-05-23) the whole document	1-3
A	✓ EP 0 534 756 A (ELI LILLY AND COMPANY) 31 March 1993 (1993-03-31) the whole document	1-3
A	✓ WO 03/037334 A (MERCK & CO., INC; ALVES, STEPHEN, E; HAMMOND, MILTON, L; WRIGHT, SAMUE) 8 May 2003 (2003-05-08) page 7, line 10 - page 8, line 9; claims 1-4; example 4	1,2
	----- -/--	

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/038221

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,A	✓ WO 2004/052858 A (ELI LILLY AND COMPANY; CLARK, BARRY, PETER; CASES-THOMAS, MANUEL, JAVI) 24 June 2004 (2004-06-24) abstract; claims; examples -----	1-3
P,A	✓ WO 2004/018441 A (ELI LILLY AND COMPANY; CASES-THOMAS, MANUEL, JAVIER; HAUGHTON, HELEN,) 4 March 2004 (2004-03-04) abstract; claims -----	1,2
P,A	✓ WO 2004/017977 A (ELI LILLY AND COMPANY; WALTER, MAGNUS, WILHELM; CLARK, BARRY, PETER; G) 4 March 2004 (2004-03-04) abstract; claims -----	1,2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/038221

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 1 and 3 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

1-3 (partially), relating to inventions 1 and 4
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-3 (partially)

Use of atomoxetine or a compound of formula (I) for treating hot flashes and vasomotor symptoms

2. claims: 1-2 (partially)

Use of racemic reboxetine or (S,S) reboxetine for treating hot flashes and vasomotor symptoms

3. claims: 1-2 (partially)

Use of a compound of formula (IA) for treating hot flashes and vasomotor symptoms

4. claims: 1-2 (partially)

Use of a morpholine derivative of formula (IB),(IC),(IG),(IH) for treating hot flashes and vasomotor symptoms

5. claims: 1-2 (partially)

Use of a compound of formula (ID) for treating hot flashes and vasomotor symptoms

6. claims: 1-2 (partially)

Use of a compound of formula (IE) for treating hot flashes and vasomotor symptoms

7. claims: 1-2 (partially)

Use of a compound of formula (IF) for treating hot flashes and vasomotor symptoms

8. claims: 1-3 (partially)

Use of a selective norepinephrine reuptake inhibitor such as defined in claim 1 for treating impulse control disorders

9. claims: 1-3 (partially)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Use of a selective norepinephrine reuptake inhibitor such as
defined in claim 1 for treating personality change due to
general medical condition

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2004/038221

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2005047272	A	26-05-2005	WO 2005047272 A1	26-05-2005
WO 2005023802	A	17-03-2005	WO 2005023802 A1	17-03-2005
WO 2004035058	A	29-04-2004	US 2004152710 A1	05-08-2004
			AU 2003282861 A1	04-05-2004
			AU 2003282862 A1	04-05-2004
			CA 2502021 A1	29-04-2004
			CA 2502032 A1	29-04-2004
			EP 1551413 A1	13-07-2005
			EP 1551379 A1	13-07-2005
			WO 2004035058 A1	29-04-2004
			WO 2004035035 A1	29-04-2004
			US 2004143008 A1	22-07-2004
			WO 2005037260 A2	28-04-2005
WO 2004035036	A	29-04-2004	US 2004180879 A1	16-09-2004
			AU 2003282830 A1	04-05-2004
			CA 2502027 A1	29-04-2004
			EP 1551380 A1	13-07-2005
			WO 2004035036 A1	29-04-2004
WO 02078691	A	10-10-2002	CA 2442410 A1	10-10-2002
			EP 1383495 A1	28-01-2004
			JP 2004525940 T	26-08-2004
			WO 02078691 A1	10-10-2002
WO 0240006	A	23-05-2002	AU 1775702 A	27-05-2002
			BR 0115301 A	14-12-2004
			CA 2426069 A1	23-05-2002
			CZ 20031339 A3	15-10-2003
			EP 1395253 A2	10-03-2004
			HR 20030384 A1	31-08-2003
			HU 0301863 A2	29-09-2003
			JP 2004529073 T	24-09-2004
			MX PA03004190 A	22-09-2003
			NO 20032156 A	13-05-2003
			PL 366119 A1	24-01-2005
			SK 5422003 A3	02-12-2003
			WO 0240006 A2	23-05-2002
			ZA 200303738 A	26-08-2004
EP 0534756	A	31-03-1993	US 5281624 A	25-01-1994
			AT 124934 T	15-07-1995
			AU 655075 B2	01-12-1994
			AU 2537092 A	01-04-1993
			BR 1100384 A3	31-08-1999
			BR 9203743 A	20-04-1993
			CA 2079161 A1	28-03-1993
			CA 2079162 A1	28-03-1993
			CN 1071416 A ,C	28-04-1993
			CZ 9202908 A3	14-04-1993
			DE 69203424 D1	17-08-1995
			DE 69203424 T2	11-01-1996
			DK 537915 T3	27-11-1995
			EP 0534756 A2	31-03-1993
			EP 0537915 A1	21-04-1993
			EP 0591584 A1	13-04-1994

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/038221

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0534756	A		FI 924305 A	28-03-1993
			HU 65375 A2	02-05-1994
			IL 103277 A	20-11-1997
			JP 3256291 B2	12-02-2002
			JP 5201961 A	10-08-1993
			JP 5238996 A	17-09-1993
			KR 221180 B1	15-09-1999
			MX 9205433 A1	01-03-1993
			NO 923710 A ,B,	29-03-1993
			NZ 244460 A	26-10-1994
			SK 290892 A3	14-02-2000
			RU 2057120 C1	27-03-1996
			ZA 9207240 A	22-03-1994
WO 03037334	A	08-05-2003	WO 03037334 A1	08-05-2003
			US 2004259850 A1	23-12-2004
WO 2004052858	A	24-06-2004	AU 2003290735 A1	30-06-2004
			WO 2004052858 A2	24-06-2004
WO 2004018441	A	04-03-2004	AU 2003268024 A1	11-03-2004
			EP 1534694 A1	01-06-2005
			WO 2004018441 A1	04-03-2004
WO 2004017977	A	04-03-2004	AU 2003269923 A1	11-03-2004
			EP 1534291 A2	01-06-2005
			WO 2004017977 A2	04-03-2004